

1/18  
HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP NON FEE AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON THE DATE INDICATED BELOW.



DATE: APR 15, 2004

PATENT

MAIL-STOP NON FEE AMENDMENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of : Group Art Unit: 1653  
Boris Skurkovich et al. :  
  
Appln. No.: 10/603,231 : Examiner: Not Yet Assigned  
  
Filed: June 25, 2003 :  
  
For: TREATMENT OF SCHIZOPHRENIA : Attorney Docket  
: No. 053663-5017-02

INFORMATION DISCLOSURE STATEMENT

It is requested that the references listed on the attached Information Disclosure Citation Form PTO-1449 be considered by the Patent Examiner in connection with the above-identified application and be made of record therein.

Copies of the references were previously cited by and/or submitted to the U.S. Patent and Trademark Office in related Application No. 10/422,119 filed April 24, 2003 (the "prior application"). The present application relies, under 35 U.S.C. § 119(e), on the filing date of U.S. Provisional Application No. 60/411,925, filed September 18, 2002. Therefore, under 37 C.F.R. § 1.98(d), copies of the references are not enclosed.

Independent consideration and acknowledgment of the listed reference(s) is respectfully requested.

Respectfully submitted,  
**BORIS SKURKOVICH ET AL.**

*April 15, 2004*  
(Date)

By: *Kathryn Doyle*  
KATHRYN DOYLE, PH.D., J.D.  
Registration No. 36,317  
MORGAN, LEWIS & BOCKIUS, LLP  
1701 Market Street  
Philadelphia, PA 19103-2921  
Telephone: (215) 963-5000  
Direct Dial: (215) 963-4723  
Facsimile: (215) 963-5001  
E-Mail: kdoyle@morganlewis.com  
Attorney for Applicants

KD/JDGB *jlf*  
Enclosure: Information Disclosure Citation Form PTO-1449



Substitute for form 1449A/PTO  
**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**  
 (use as many sheets as necessary)

Sheet 1 of 6

		<i>Complete if Known</i>	
Application Number		10/603,231	
Filing Date		June 25, 2003	
First Named Inventor		Boris Skurkovich	
Group Art Unit		1653	
Examiner Name		Not Yet Assigned	
Attorney Docket Number		053663-5017-02	

U.S. PATENT DOCUMENTS			
Exr Initials	U.S. Patent Document Number	Kind Code (if known)	Name of Inventor or Applicant of Cited Document
	4,362,155		Simon V. Skurkovich
	4,605,395		Christian Sainte Rose et al
	5,800,988		Cecile Casterman et al.
	5,759,808		Cecile Casterman et al.
	5,840,526		Cecile Casterman et al.
	6,015,695		Cecile Casterman et al.
	4,704,362		Keiichi Itakura et al
	4,824,432		Simon Skurkovich et al
	6,180,370		Cary L. Queen et al
	6,329,511		Maximiliano Vasquez et al.
	5,888,511		Simon V. Skurkovich

FOREIGN PATENT DOCUMENTS				
Exr Initials	Foreign Patent Document		Date of Publication of Cited Document MM-DD-YYYY	
	Country Code	Number	Kind Code (if known)	T <sub>1</sub>
	WO	87/02671		Randy Robinson et al
				May 7, 1987

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Exr Initials	Include Name of Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal., serial., symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	<b>ADERKA et al., Correlation Between Serum Levels of Soluble Tumor Necrosis Factor Receptor and Disease Activity in Systemic Lupus Erythematosus, Arthritis and Rheumatism, Vol. 36, No. 8, 1111-1120 (August, 1993)</b>
	<b>ALTOMONTE et al., Serum Levels of Interleukin-1b, Tumour Necrosis Factor-a and Interleukin-2 in Rheumatoid Arthritis: Correlation With Disease Activity, Clin. Rheum. Vol. 11, No. 2, pp. 202-205, (1992)</b>
	<b>AROLT et al., Decreased in vitro production of interferon-gamma and interleukin-2 in whole blood of patients with schizophrenia during treatment, Molecular Psychiatry, Vol. 5, 150-158 (March, 2000)</b>
	<b>BAYER et al., The Avidin-Biotin Complex in Affinity Cytotechnology, Methods in Enzymology, Vol. 62:308 (1979), Academic Press, Inc. (Book; Not Submitted)</b>
	<b>BEVAN et al., Interferon-Induced Parotitis and Epididymitis, The Lancet 2:561 (September, 1985)</b>
	<b>BEYCHOK, Cells of Immunoglobulin Synthesis, (1979) Academic Press, New York (Book; Not Submitted)</b>
	<b>BIGLINO et al., Spontaneous Release of Interferon as a Predictor of Clinical Evolution in HIV-Positive Subjects, Infection 19(I): 7/11-11/17 (1991)</b>
	<b>BIRD et al., Single-Chain Antigen-Binding Proteins, Science Vol. 242, pp. 423-426, April, 1988.</b>
	<b>BRAHN et al., Effects of Tumor Necrosis Factor Alpha (TNF-<math>\alpha</math>) on Collagen</b>



	Arthritis, Lymphokine and Cytokine Research, Vol. 11, No. 5 pp. 253-256, (1992)	
	BRENNAN et al., TNF $\alpha$ - A Pivotal Role in Rheumatoid Arthritis?, British Journal of Rheumatology, 31(5):293-298 (1992)	
	BURTON, Dennis R., Human Monoclonal Antibodies: Achievement and Potential, Hospital Practice, pp. 67-74, August 1992.	
	CAMPBELL, A.M., Monoclonal Antibody Technology: Laboratory Techniques in Biochemistry and Molecular Biology, Elsevier Science Publishers Amsterdam, The Netherlands (1984) (Book; Not Submitted)	•
	CARPENTER et al., The Pathogenesis of Autoimmunity in New Zealand Mice, Lab Invest. Vol. 23, No.6, pp 628-634, (1970)	
	CHU et al., Detection of Cytokines at the Cartilage/Pannus Junction in Patients With Rheumatoid Arthritis: Implications for the Role of Cytokines in Cartilage Destruction and Repair, British Journal of Rheumatology, Vol. 31, No. 10 pp. 653-661 (1992)	
	CONLON et al., Exacerbation of Symptoms of Autoimmune Disease in Patients Receiving Alpha-Interferon Therapy, Cancer, Vol. 65, pp. 2237-2242, May 15, 1990.	
	DANIS et al., Circulating Cytokine Levels in Patients With Rheumatoid Arthritis: Results of a Double Blind Trial With Sulphasalazine, Ann. Rheum. Disease 51(8):946 (1992)	
	DIAGNOSTIC AND STATISTICAL MANUAL OF PSYCHIATRIC DISORDERS (DSM IV) American Psychiatric Association, 4th Ed. Washington D.C. (1994) (Book; Not Submitted)	•
	DELEURAN et al., Localization of Tumor Necrosis Factor Receptors in the Synovial Tissue and Cartilage-Pannus Junction in Patients With Rheumatoid Arthritis, Arthritis and Rheumatology, Vol. 35, No. 10, pp. 1170-1178 (1992)	
	DeSTEFANO et al., Acid-Labile Human Leukocyte Interferon in Homosexual Men With Kaposi's Sarcoma and Lymphadenopathy, The Journal of Infectious Diseases, Vol. 146, No. 4, pp. 451-455, October, 1982.	
	DORSETT et al., Anti-Lymphocyte Antibodies in Patients With the Acquired Immune Deficiency Syndrome, The American Journal of Medicine, Vol. 78, pp. 621-626, April, 1985.	
	ELLIOTT et al., Treatment of Rheumatoid Arthritis With Chimeric Monoclonal Antibodies to TNF- $\alpha$ Safety, Clinical Efficacy and Control of the Acute-Phase Response, J. Cell. Biochem. Suppl. 17B:145 (1993).	
	ELLIOTT et al., Repeated Therapy With Monoclonal Antibody to Tumour Necrosis Factor $\alpha$ (cA2) in Patients With Rheumatoid Arthritis, The Lancet, Vol. 344, pp. 1125-1127, October 22, 1994.	
	ENGLEMAN et al., Treatment of NZB/NZW F <sub>1</sub> Hybrid Mice With Mycobacterium Bovis Strain BCG or Type II Interferon Preparations Accelerates Autoimmune Disease, Arthritis and Rheumatism, Vol. 24, pp. 1396-1402, November, 1981.	
	ENGVALL et al., Enzyme-Linked Immunosorbent Assay, Elisa III. Quantitation of Specific Antibodies by Enzyme-Labeled Anti-Immunoglobulin in Antigen-Coated Tubes, The Journal of Immunology, Vol. 109, pp. 129-135, Copyright 1972 by The Williams & Wilkins Co., Printed in U.S.A.	



FATTOVICH et al., Autoantibodies During $\alpha$ -Interferon Therapy for Chronic Hepatitis B, <i>Journal of Medical Virology</i> , Vol. 34, pp. 132-135, (1991)
FELDMANN et al., Interferons and Autoimmunity, IFN9, Academic Press, p. 75 (1987)
FOULIS et al., Immunoreactive $\alpha$ -Interferon in Insulin-Secreting $\beta$ Cells in Type 1 Diabetes Mellitus, <i>The Lancet</i> , Vol. 2, pp. 1423-1427, December 19, 1987.
GAUGHRAN, Immunity and schizophrenia: autoimmunity, cytokines, and immune responses, <i>Int Rev Neurobiol.</i> 2002, 52:275-302.
GENDelman et al., Induction of IFN- $\alpha$ in Peripheral Blood Mononuclear Cells by HIV-Infected Monocytes, <i>The Journal of Immunology</i> , Vol. 148, pp. 422-429, January 15, 1992.
GILLAM et al., Site-Specific Mutagenesis Using Synthetic Oligodeoxyribonucleotide Primers: I. Optimum Conditions and Minimum Oligodeoxyribonucleotide Length, <i>Gene</i> Vol. 8, pp. 81-97 (1979), Elsevier/North-Holland Biomedical Press
GODING, Conjugation of Antibodies With Fluorochromes: Modifications to the Standard Methods, <i>Journal of Immunological Methods</i> , 13:215-226 (1976), Elsevier/North-Holland Biomedical Press.
GRANINGER et al., Induction of Systemic Lupus Erythematosus by Interferon- $\gamma$ In a Patient With Rheumatoid Arthritis, <i>The Journal of Rheumatology</i> , Vol. 18, pp. 1621-1622, 1991.
GRINGERI et al., Anti-Alpha Interferon Immunization: Safety and Immunogenicity in Asymptomatic HIC Positive Patients at High Risk of Disease Progression, <i>Cellular and Molecular Biology</i> , Vol. 41, No.3, pp. 381-387 (1995)
GRINGERI et al., Absence of Clinical, Virological, and Immunological Signs of Progression in HIC-1-Infected Patients Receiving Active Anti-Interferon- $\alpha$ Immunization: A 30-Month Follow-up Report, <i>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</i> , 13:55-67 (1996)
GU et al., Construction and Expression of Mouse-human Chimeric Antibody SZ-51 Specific for Activated Platelet P-selectin, <i>Thrombosis and Hemostasis</i> 77 (4):755-759 (1997)
HAMERS-CASTERMAN et al., Naturally occurring antibodies devoid of light chains. <i>Nature</i> . 1993 June 3 363(6428):446-448.
HARLOW et al., <i>In Antibodies: A Laboratory Manual</i> , Cold Spring Harbor, NY (Book; Not Submitted) •
HENNIGER et al., Interferon- $\beta_{1b}$ Treatment Decreases Tumor Necrosis Factor- $\alpha$ and Increases Interleukin-6 Production in Multiple Sclerosis, <i>Neurology</i> Vol. 46, 1633-1639 , June 1996
HEREMANS et al., Interferon Treatment of NZB Mice: Accelerated Progression of Autoimmune Disease, Infection and Immunity, Vol. 21, pp. 925-930, Printed in USA, September 1978.
HESS et al., Tumor Necrosis Factor and Interferon as Prognostic Factors in Human Immunodeficiency Virus (HIV) Infection, <i>Infection</i> 19, Suppl 2:S93-97 (1991)
HIRANO et al., Interleukin-6 and Its Relation to Inflammation and Disease, <i>Clinical Immunology, and Immunopathology</i> , Vol. 62, No. 1, pp.S60-S65, January, 1992., Academic Press, Inc.



HOLT et al., Cytokine Inter-Relationships and Their Association With Disease Activity in Arthritis, <i>British Journal of Rheumatology</i> , Vol. 31, pp. 725-733, (1992).
HOOKS et al., Immune Interferon in the Circulation of Patients With Autoimmune Disease, <i>The New England Journal of Medicine</i> , Vol. 301, No. 1, July 5, 1979.
HUSTON et al., Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced in <i>Escherichia Coli</i> , <i>Proc. Nat'l. Acad. Sci. USA</i> , Vol 85, pp. 5879-5882, August, 1988
JOHNSON et al., The Role of Antimyosin Antibodies in Acute Myocardial Infarction, <i>Seminars in Nuclear Medicine</i> , Vol. 19, No. 3, pp. 238-246, July, 1989.
LARREY et al., Exacerbation of Multiple Sclerosis After the Administration of Recombinant Human Interferon Alfa, <i>JAMA</i> , Vol. 261, p. 2065, April 14, 1989.
LAU et al., Regulation of Tumor Necrosis Factor Receptor Expression by Acid-Labile Interferon- $\alpha$ From AIDS Sera, AIDS Research and Human Retroviruses, Vol. 7, No. 6, pp.545-552, 1991, Mary Ann Liebert, Inc., Publishers.
LEINONEN et al., Circulating Immune Complexes Containing Chlamydial Lipopolysaccharide in Acute Myocardial Infarction, <i>Microbial Pathogenesis</i> , Vol. 9, pp. 67-73, 1990
LIBIKOVA et al., Orbiviruses of the Kemerovo Complex and Neurological Diseases, <i>Med. Microbiol. Immunol.</i> , Vol. 166, pp. 255-263 (1978)
LIBIKOVA et al., Assay of Interferon and Viral Antibodies in the Cerebrospinal Fluid in Clinical Neurology and Psychiatry, <i>Acta Biol. Med. Germ.</i> , Band 38, Seite 879-893 (1979)
LINK et al., Increased Transforming Growth Factor- $\beta$ , Interleukin-4, and Interferon- $\gamma$ in Multiple Sclerosis, <i>American Neurological Association</i> , Vol. 36, pp. 379-386 (1994)
LIVDEN, et al., In Situ Localization of Interferons in Psoriatic Lesions, <i>Arch Dermalot Res.</i> 281, pp. 392-397, (1989)
MACHOLD et al., Interferon- $\gamma$ Induced Exacerbation of Systemic Lupus Erythematosus, <i>J. Rheumat.</i> 17(6):83 1-832 (1990)
MATSUYAMA et al., Cytocidal Effect of Tumor Necrosis Factor on Cells Chronically Infected with Human Immunodeficiency Virus (HIV): Enhancement of HIV Replication, <i>Journal of Virology</i> , Vol. 63, No. 6, June 1989, pp. 2504-2509
MEIJER et al., Profiles of Cytokines (TNF $\alpha$ and IL-6) and Acute Phase Proteins (CRP and $\alpha$ 1AG) Related to the Disease Course in Patients With Systemic Lupus Erythematosus, <i>Lupus</i> , Vol. 2, pp. 359-365, 1993.
MONTALBAN et al., Antiphospholipid Antibodies in Cerebral Ischemia, Stroke, Vol. 22, pp. 750-753 (1991)
NAUDIN et al., A differential role for interleukin-6 and tumor necrosis factor-alpha in schizophrenia? <i>Schizophr Res.</i> 1997 Aug 29;26(2-3):227-33.
PANITCH et al., Exacerbations of Multiple Sclerosis in Patients Treated With Gamma Interferon, <i>The Lancet</i> 1:893, April 18, 1987.
PAULUS et al., Analysis of Improvement in Individual Rheumatoid Arthritis Patients Treated With Disease-Modifying Antirheumatic Drugs, Based on the Findings in Patients Treated With Placebo, <i>Arthritis Rheum.</i> 33:477-484(1990)
PREBLE et al., Systemic Lupus Erythematosus: Presence in Human Serum of an Unusual Acid-Labile Leukocyte Interferon, <i>Science</i> , Vol. 216, No. 423, pp. 429-431,



April 1982.
PREBLE et al., Serum Interferon in Patients With Psychosis, <i>Am. J. Psychiatry</i> 142:10 October, 1985.
QUEEN et al., Cell-Type Specific Regulation of a $\kappa$ Immunoglobulin Gene by Promoter and Enhancer Elements, <i>Immunol. Rev.</i> , 89, 49-68 (1986)
QUESADA et al., Clinical Toxicity of Interferons in Cancer Patients: A Review, <i>Journal of Clinical Oncology</i> , Vol. 4, No. 2, pp. 234-243, February, 1986.
QUESADA et al., Psoriasis and Alpha-Interferon, <i>The Lancet</i> 2:1466, June 28, 1986.
REMY et al., Experimental Autoimmune Thyroiditis Induced by Recombinant Interferon- $\gamma$ , <i>Immunology Today</i> , Vol. 8, No. 3, 73 (1987)
ROBERTS et al., Generation of an Antibody With Enhanced Affinity and Specificity for its Antigen by Protein Engineering, <i>Nature</i> , 328:731-734 (1987)
RONNBLOM, et al., Possible Induction of Systemic Lupus Erythematosus by Interferon- $\alpha$ Treatment in a Patient With a Malignant Carcinoid Tumour, <i>Journal of Internal Medicine</i> , Vol. 227, pp. 207-210 (1990)
RONNBLOM et al., Autoimmunity After Alpha-Interferon Therapy for Malignant Carcinoid Tumors, <i>Annals of Internal Medicine</i> , Vol. 115, 178-183 (1991)
SAMBROOK et al., 1989, Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, NY. (Book; Not Submitted)
SASTRY et al., 1989, Cloning of the immunological repertoire in <i>Escherichia coli</i> for generation of monoclonal catalytic antibodies: construction of a heavy chain variable region-specific cDNA library. <i>Proc. Nat'l. Acad. Sci. USA</i> , 86: 5728-5732
SCHATTNER et al., Review: Interferons and Autoimmunity, <i>Am. J. Med. Sci.</i> Vol. 295, No. 6, pp. 532-544, June, 1988.
SCHILLING et al., Development of Systemic Lupus Erythematosus After Interferon Therapy for Chronic Myelogenous Leukemia, <i>Cancer</i> Vol. 68, pp. 1536-1537, October 1, 1991.
SCOPES et al., Protein Purification, Springer-Verlag, New York, NY (1982) (Book; Not Submitted)
SELIGMANN et al., 1979, Heavy chain diseases: current findings and concepts. <i>Immunological Review</i> 48: 145-167
SHARIEF et al., Association Between Tumor Necrosis Factor- $\alpha$ and Disease Progression in Patients With Multiple Sclerosis, <i>The New England Journal of Medicine</i> , Vol. 325, No. 7, pp. 467-472 August 15, 1991.
SHIOZAWA et al., Interferon-Alpha in Lupus Psychosis, Arthritis and Rheumatism, Vol. 35, pp. 417-422, April, 1992.
SINHA et al., Autoimmune Diseases: The Failure of Self Tolerance, <i>Science</i> , Vol. 248, pp. 1380-1387, June 15, 1990.
SKURKOVICH et al., Immunosuppressive Effect of an Anti-interferon Serum, <i>Nature</i> , Vol. 247, pp. 551-552, February 22, 1974
SKURKOVICH et al., The Probable Role of Interferon in Allergy, <i>Annals of Allergy</i> Vol. 35, pp. 356-360, December, 1975.
SKURKOVICH et al., Lymphocytes' Cytotoxicity Towards Cells of Human Lymphoblastoid Lines in Patients With Rheumatoid Arthritis and Systemic Lupus Erythematosus, <i>Annals of Allergy</i> Vol. 39, pp. 344-350, November, 1977.



	SKURKOVICH et al., Interferon Production by Patients With Systematic Lupus Erythematosus (SLE) or Rheumatoid Arthritis (RA), Abstracts – Second Annual International Congress for Interferon Research (1981)	
	SKURKOVICH et al., Aberrant IFN May Help HIV Survive and Replicate; Its Removal in AIDS Patients May Halt This Process and Help Restore the Immune System, Journal of Interferon Research, Vol. 12, Suppl. 1:S110 (1992)	
	SKURKOVICH et al., A Disturbance of Interferon Synthesis With the Hyperproduction of Unusual Kinds of Interferon can Trigger Autoimmune Disease and Play a Pathogenetic Role in AIDS: The Removal of These Interferons Can Be Therapeutic, Medical Hypotheses, Vol. 41, pp. 177-185 (1993)	
	SKURKOVICH et al., A Disturbance of Interferon Synthesis With the Hyperproduction of Unusual Kinds of Interferon can Trigger Autoimmune Disease and Play a Pathogenetic Role in AIDS: The Removal of These Interferons Can Be Therapeutic, Medical Hypotheses, Med. Hypoth. Vol. 42, pp. 27-35 (1994)	
	STERNBERGER et al., The Unlabeled Antibody Enzyme Method of Immunohistochemistry Preparation and Properties of Soluble Antigen-Antibody Complex (Horseradish Peroxidase-Antihorseradish Peroxidase) and its use in Identification of Spirochetes The Journal of Histochemistry and Cytochemistry, Vol. 18, No. 5, pp. 315-333	
	ST. GROTH et al., Production of Monoclonal Antibodies: Strategy and Tactics, Journal of Immunological Methods, Vol. 35k, pp. 1-21 (1980)	
	TUSZYNSKI et al., Thrombospondin Promotes Platelet Aggregation, Blood, Vol. 72, pp. 109-115, July, 1988.	
	VADHAN-RAJ et al., Immunological Variables as Predictors of Prognosis in Patients With Kaposi's Sarcoma and the Acquired Immunodeficiency Syndrome, Cancer Research, Vol. 46, pp. 417-425, January 1986.	
	VAN SNICK et al., Interleukin-6: An Overview, Annual Rev. Immunol. Vol. 8, pp. 253-278 (1990)	
	VILCEK et al., In AIDS: The Epidemic of Kaposi's Syndrome and Opportunistic Infections, A. E. Friedman-Kien & L. J. Lauberstein, eds. Masson Publishing, NY, NY (1986)	*
	WARD et al., 1989, Binding activities of a repertoire of single immunoglobulin variable domains secreted from Escherichia coli. Nature, 341: 544-546	
	WOOD et al., In Situ Hybridization of IL-6 in Rheumatoid Arthritis, Clin & Exp. Immunol 87(2):183 (1992)	
	WINNACKER, 1987, "From Genes to Clones," VCH Publishers, New York, N.Y (Book; Not Submitted)	*
	WRIGHT et al., Genetically Engineered Antibodies: Progress and Prospects, Critical Rev. in Immunol. 12(3,4):125-168 (1992)	

- References are books